

PATENT APPLICATION

**DEVICES AND METHODS FOR CARDIAC ANNULUS  
STABILIZATION AND TREATMENT**

**Inventor:** NIEL F. STARKSEN, a citizen of The United States,  
residing at 12119 Edgecliff Place  
Los Altos Hills, California 94022.

**Assignee:** Guided Delivery Systems, Inc.  
12119 Edgecliff Place,  
Los Altos, CA, 94022

**Status:** Small Entity

60015397 v1

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 650-326-2400

## DEVICES AND METHODS FOR CARDIAC ANNULUS STABILIZATION AND TREATMENT

### CROSS REFERENCE TO RELATED APPLICATIONS

5 [0001] The present application is related to, and contains subject matter in common with, U.S. Patent Application Serial No. 10/461043 (Attorney Docket No. 16886-000310), filed on June 13, 2003, which is assigned to the assignees of the present invention, and which is hereby incorporated fully by reference.

### BACKGROUND OF THE INVENTION

10 [0002] 1. Field of the Invention. The present invention relates generally to medical devices and methods. More particularly, the invention relates to devices and methods for enhancing cardiovascular valve repair, especially the repair of heart valves such as the mitral and tricuspid valves.

[0003] In recent years, many advances have been made to reduce the invasiveness of cardiac surgery. In an attempt to avoid open, stopped-heart procedures, which may be accompanied by high patient morbidity and mortality, many devices and methods have been developed for operating on a heart through smaller incisions, operating on a beating heart, and even performing cardiac procedures via transvascular access. Different types of cardiac procedures, such as cardiac ablation techniques for treating atrial fibrillation, stenting  
15 procedures for atherosclerosis, and valve repair procedures for treating conditions such as mitral valve regurgitation have experienced significant technological advances. In implementing many minimally invasive cardiac surgery techniques, especially beating-heart techniques, one of the most significant challenges is exposing and stabilizing a portion of cardiac tissue to be operated upon. Another challenge, once exposure and stability are  
20 achieved, is to effectively deploy a given treatment into or on the target cardiac tissue using minimally invasive devices.

[0004] One type of cardiac surgery which may benefit from less invasive techniques is heart valve repair. Traditional treatment of heart valve stenosis or regurgitation, such as mitral or tricuspid regurgitation, typically involves an open-heart surgical procedure to  
25 replace or repair the valve. Valve repair procedures typically involve annuloplasty, a set of techniques designed to restore the valve annulus shape and strengthen the annulus.

Conventional annuloplasty surgery generally requires a large incision into the thorax of the patient (a thoracotomy), and sometimes a median sternotomy (cutting through the middle of the sternum). These open heart, open chest procedures routinely involve placing the patient on a cardiopulmonary bypass machine for sustained periods so that the patient's heart and lungs can be artificially stopped during the procedure. Finally, valve repair and replacement procedures are typically technically challenging and require a relatively large incision through the wall of the heart to access the valve.

[0005] Due to the highly invasive nature of open heart valve repair or replacement, many patients, such as elderly patients, patients having recently undergone other surgical procedures, patients with comorbid medical conditions, children, late-stage heart failure patients, and the like, are often considered too high-risk to undergo heart valve surgery and are relegated to progressive deterioration and cardiac enlargement. Often, such patients have no feasible alternative treatments for their heart valve conditions.

[0006] To obviate this situation, a number of devices and methods for repairing cardiac valves in a less invasive manner have been described. Some devices provide for heart valve repair through minimally invasive incisions or intravascularly, while others improve upon open heart surgical procedures on beating hearts, stopped hearts or both. For example, several improved devices and methods for heart valve repair are described in one or more patent applications filed by the inventors of the present invention and assigned to the assignee of the present invention. For further description of such devices and methods, reference may be made to U.S. Patent Application Serial No. 10/461043 (Attorney Docket No. 16886-000310), filed on June 13, 2003, previously incorporated by reference.

[0007] As mentioned above, some of the difficulties in performing minimally invasive intracardiac surgery include exposing and stabilizing an area of cardiac tissue to be operated upon and effectively operating on that tissue using minimally invasive instruments. Sufficient exposure is essential for allowing the physician to locate and perform a procedure on the targeted cardiac tissue. Stabilization further facilitates an intracardiac procedure, especially in a beating heart. In minimally invasive, beating heart surgery on a cardiac valve annulus, exposure and stabilization are especially challenging, due to rapid movement of the annulus and the heart, the small size of the annulus, and the blood-filled surgical field. While a cardiac valve may be visualized via transesophageal echocardiogram (TEE), it is much more difficult to locate the annulus itself, as it is basically a small band of fibrous tissue.

Exposure of the annulus is essential, however, since annular tissue is far stronger than surrounding valve leaflet and heart wall tissue, and repair procedures performed on a valve annulus will be much more effective than those performed on other tissue adjacent the annulus. Even after a valve annulus is exposed and stabilized, it may still be challenging to effectively and efficiently operate on the annulus to repair the valve, using minimally invasive devices.

[0008] Many minimally invasive or "less invasive" surgical procedures other than heart valve repair would also benefit from improved exposure and/or stabilization. For example, improved exposure and stabilization could facilitate other cardiac procedures, such as accessing the coronary sinus for placement of an implantable device or for performing a procedure, placing pacemaker leads in one or more areas of the heart, ablation procedures such as ablation around the pulmonary veins to treat atrial fibrillation, atrial-septal defect repair procedures, and the like. Improved stabilization and exposure could also be used to enhance non-cardiac procedures such as cinching or otherwise treating a bladder, stomach, gastroesophageal junction, vascular structure, gall bladder or the like.

[0009] Therefore, it would be beneficial to have devices and methods for enhancing exposure and/or stabilization in transvascular, minimally invasive and other "less invasive" surgical procedures, such as heart valve repair and other cardiac procedures. Ideally, for example, such devices and method could be used for exposing and stabilizing a cardiac valve annulus for performing a valve repair procedure. Ideally, such devices and methods could be used in minimally invasive or "less invasive" beating heart procedures performed via a variety of access routes, such as transvascular or transthoracic. Also ideally, some devices might be used for exposing a valve annulus, others might expose and stabilize an annulus, and still others might expose, stabilize and administer a therapy to an annulus, thus providing a physician with numerous procedural options. At least some of these objectives will be met by the present invention.

[0010] 2. Description of the Background Art. Published U.S. Application 2002/0156526 describes a catheter-based method for performing annuloplasty. Published U.S. Application 2002/0042621 describes a heart valve annuloplasty system with constrictable plication bands which are optionally attached to a linkage strip. Published U.S. Application 2002/0087169 describes a remote controlled catheter system which can be used to deliver anchors and a tether for performing an annuloplasty procedure. Other patent

publications of interest include WO01/26586; US2001/0005787; US2001/0014800; US2002/0013621; US2002/0029080; US2002/0035361; US2002/0042621; US2002/0095167; and US2003/0074012. U.S. patents of interest include 4,014,492; 4,042,979; 4,043,504; 4,055,861; 4,700,250; 5,366,479; 5,450,860; 5,571,215; 5,674,279; 5,709,695; 5,752,518; 5,848,969; 5,860,992; 5,904,651; 5,961,539; 5,972,004; 6,165,183; 6,197,017; 6,250,308; 6,260,552; 6,283,993; 6,269,819; 6,312,447; 6,332,893; and 6,524,338. Publications of interest include De Simone et al. (1993) Am. J. Cardiol. 73:721-722, and Downing et al. (2001) Heart Surgery Forum, Abstract 7025.

## BRIEF SUMMARY OF THE INVENTION

[0011] Devices and methods of the present invention are generally used to facilitate transvascular, minimally invasive and other "less invasive" surgical procedures, by enhancing exposure, stabilization and/or the like of a tissue or structure upon which a procedure is to be performed. "Less invasive," for the purposes of this application, means any procedure that is less invasive than traditional, large-incision open surgical procedures. Thus, a less invasive procedure may be an open surgical procedure involving one or more relatively small incisions, a transvascular percutaneous procedure, a transvascular procedure via cut-down, a laparoscopic or other endoscopic procedure, or the like. Generally, any procedure in which a goal is to minimize or reduce invasiveness to the patient may be considered less invasive.

Furthermore, although the terms "less invasive" and "minimally invasive" may sometimes be used interchangeably in this application, neither these nor terms used to describe a particular subset of surgical or other procedures should be interpreted to limit the scope of the invention. Generally, stabilization/exposure devices and methods of the invention may be used in performing or enhancing any suitable procedure.

[0012] As mentioned above, the present application typically describes devices and methods for stabilization and/or exposure in the context of heart valve repair, and more specifically mitral valve repair to treat mitral regurgitation. It should be emphasized, however, that devices and methods of the invention may be used in any suitable procedure, both cardiac and non-cardiac. For example, they may be used in procedures to repair any heart valve, to repair an atrial-septal defect, to access and possibly perform a procedure from (or through) the coronary sinus, to place one or more pacemaker leads, to perform a cardiac ablation procedure such as ablating around pulmonary veins to treat atrial fibrillation, and/or the like. In other embodiments, the devices and methods may be used to enhance a

laparoscopic or other endoscopic procedure on any part of the body, such as the bladder, stomach, gastroesophageal junction, vasculature, gall bladder, or the like. Therefore, although the following description typically focuses on mitral valve and other heart valve repair, such description should not be interpreted to limit the scope of the invention as defined by the claims.

[0013] That being said, the present invention generally provides devices and methods for enhanced stabilization, exposure and/or treatment of a cardiac valve annulus. Methods generally involve introducing a stabilizing member beneath one or more leaflets of a heart valve to engage the ventricular side of the annulus at an intersection between the leaflets and the interior ventricular wall of the heart. The stabilizing member will usually be curved or C-shaped to conform to at least a portion of the ventricular side of the annulus, and force is applied to the stabilizing member to engage and stabilize the valve annulus. By "stabilize," it is meant that the annulus will be at least partially immobilized relative to the cardiac tissue surrounding the annulus, at least partially delineated or exposed relative to cardiac tissue surrounding the annulus, or both. For example, in some instances "stabilization" may not involve immobilizing annular tissue but may instead involve moving or positioning annular tissue in such a way to allow enhanced visualization of that tissue relative to surrounding tissues.

[0014] As just mentioned, in addition to stabilizing, methods and apparatus of the present invention may also help expose, position, or delineate the valve annulus, to enhance the physician's ability to view and operate on the annular tissue. Some embodiments also include a second stabilizing member, to be introduced above the leaflets, allowing a physician to grasp or clamp annular tissue between the upper and lower stabilizing members for further stabilization. Various embodiments further provide for treatment of a valve annulus. For example, either the upper or lower stabilizing member may include actuators or effectors for performing any one or more of a variety of interventions. For example, either or both stabilizing members may be adapted to deliver devices for constricting or reshaping the valve annulus to treat regurgitation or other conditions. The devices may comprise anchors, tethered anchors, rings, or the like for reinforcing or cinching the annulus. In a specific example, the stabilizing member may be configured to hydraulically or otherwise deliver a series of tethered hooks, tethered clips or other tethered anchors or fasteners for engaging and cinching valve annulus tissue to decrease the diameter of a regurgitant valve. The stabilizer(s) will also be adaptable for delivering other therapies, including applying

radiofrequency energy (or other heat sources) to shrink the collagen tissue in the annulus, delivering bulking agents, delivering drugs and biological agents such as growth factors, delivering agents for providing cell dedifferentiation, and/or the like.

**[0015]** In most cases, the methods of the present invention will be performed on a beating heart. Access to the beating heart may be accomplished by any available technique, including intravascular, transthoracic, and the like. In addition to beating heart access, the methods of the present invention may be used for intravascular stopped heart access as well as stopped heart open chest procedures.

**[0016]** In one aspect of the invention, a method for stabilizing a valve annulus of a heart for performing a procedure on the valve annulus involves first introducing at least a first stabilizing member beneath one or more leaflets of a valve of the heart to engage an intersection between at least one leaflet and the interior ventricular wall of the heart. Force is then applied to the first stabilizing member to stabilize the valve annulus. Usually, the stabilizing member engages the ventricular annulus (in the case of a mitral valve), and applying force comprises drawing the stabilizing member upwardly against the annulus to immobilize the annular tissue relative to the surrounding tissue. When a second stabilizing member is employed, applying force comprises applying opposed forces with the "upper and lower" stabilizing members to further stabilize the annular tissue. Such methods may be used on any of a number of cardiac or circulatory valves or other body structures such as valves in body lumens, but in one embodiment, for example, the first stabilizing member is passed beneath the posterior leaflet of the mitral valve. In addition to stabilizing the annular tissue, applying pressure with the stabilization device may also expose the valve annulus from surrounding tissue of the heart, for improved visualization and access by the physician.

**[0017]** In some embodiments, introducing the device comprises advancing a flexible, elongate catheter through vasculature of a patient to the heart, with at least a first stabilizing member comprising a shape-changing member at a distal end of the flexible elongate catheter. The catheter may be introduced through the vasculature with the shape-changing stabilizing member in a generally straight, flexible configuration. Once it is in place beneath the leaflet at the intersection between the leaflet and the interior ventricular wall, the shape of the stabilizing member is changed to conform to the annulus and usually the shape is "locked" to provide sufficient stiffness or rigidity to permit the application of force from the stabilizing member to the annulus. Shaping and optionally locking the stabilizing member

may be accomplished in any of a number of ways, such as applying tension to tensioning cord(s), as described in detail below.

[0018] In transthoracic and other embodiments, the stabilizing member may be pre-shaped, and the method may simply involve introducing the stabilizing member(s) under and/or over the valve leaflets. The pre-shaped stabilizing member(s) may be rigid or formed from a shape memory material such as nitinol, spring stainless steel, or the like.

[0019] Force applied to the first stabilizing member is often upwardly directed, though lateral forces are also possible. In addition to stabilizing with force from below the annulus, stabilizing may optionally include introducing a second stabilizing member over the valve leaflets. By moving the second stabilizing member toward the first stabilizing member, a physician may grip or clamp all or a portion of the valve annulus.

[0020] In another aspect, a method for performing a procedure on a stabilized valve annulus includes advancing a flexible, elongate stabilizing catheter through vasculature of a patient to the heart. Next, a shape-changing stabilizing member on the catheter is positioned beneath one or more leaflets of a valve of the heart to engage the lower or ventricular annulus at an intersection between at least one leaflet and an interior ventricular wall of the heart. The shape of the stabilizing member is then changed and optionally locked to conform to the annulus, and an upward and/or other force is applied to the stabilizing member to stabilize the valve annulus.

[0021] In still another aspect of the present invention, a method for constricting a valve annulus in a beating heart comprises introducing at least a first stabilizing member beneath one or more leaflets of a valve of the heart to engage the annulus at an intersection between at least one leaflet and an interior ventricular wall of the heart. Force is then applied to the first stabilizing member to stabilize the valve annulus. A plurality of individual anchors, such as hooks, clips, barbs, T-tags, rings, anchors made of resorbable polymers such as polylactic acid or polyglycolic acid, or the like, may then be placed at circumferentially spaced-apart locations about at least a portion of the valve annulus while the valve annulus remains stabilized. The anchors may then be cinched via a tether to circumferentially tighten the annulus. Optionally, the method may further include introducing at least a second stabilizing member over the valve leaflets and moving the second stabilizing member toward the first stabilizing member to further stabilize the annulus. In some embodiments, securing the anchors comprises driving the anchors from one of the first and second stabilizing members.



Driving the anchors, in turn, may involve inflating an expandable balloon in one of the members to force the anchors at least partially out of the member into tissue of the valve annulus. Optionally, securing the anchors may also involve driving the anchors through tissue of the valve annulus into an anchor receiving piece coupled with the other stabilizing member.

[0022] Throughout the present application, the term "anchor" is frequently used to a device for coupling with a valve annulus or other bodily structure. For the purposes of this application, "anchor" means any fastener or other attachment device. Thus, an anchor may be a hook, such as a curved hook or a straight, barbed hook, a clip, a T-tag, a ring, an adhesive strip, a shape-memory fastening device or any other fastener. Furthermore, anchors may be made of any suitable material. For example, an anchor may be made of a metal, such as stainless steel, or may alternatively be made of a bioresorbable material such as polylactate or polyglycolate, such that over time, after a body structure has repaired, the anchors may be resorbed. Therefore, although various examples of anchors are described below and various terms such as "hooks" may be used to describe fastening devices of the invention, these terms should not be interpreted to limit the scope of the invention as defined by the claims.

[0023] In yet another aspect of the invention, a device for enhancing a surgical procedure on a valve annulus of a heart includes an elongate body having a proximal end and a distal end and at least a first stabilizing member at the distal end of the shaft. Generally, the first stabilizing member is passable under one or more leaflets of a valve of the heart to engage an intersection between at least one leaflet and an interior ventricular wall of the heart. In some embodiments, the elongate body comprises a rigid shaft. In alternative embodiments, the elongate body comprises a flexible catheter, so that the first stabilizing member may be passed into the heart and under the one or more leaflets via a transvascular approach.

[0024] The first stabilizing member may comprise a shape-changing portion. By "shape-changing," it is meant that at least a segment of the stabilizing member may be transitioned between (a) a straight or flexible configuration (to facilitate introduction) and (b) a fixed-shape configuration, generally a curved or C-shaped segment which conforms to the shape of the valve annulus. Such shape-changing may be accomplished by a variety of mechanical approaches. In some embodiments, for example, the first stabilizing member may include a slotted, segmented or sectioned tube coupled with one or more pull cords. Tension may be applied to one pull cord to bend the segmented tube into a C-shape, while tension may be

applied to the other cord to bend the tube up, or proximally. Generally, a segmented tube and two pull cords can be used to shape a stabilizing member around two bends having any desired configuration. In another embodiment, a shape-memory material may be included in the first stabilizing member, and introducing fluid into the member may cause it to change  
5 from a straight configuration to a C-shape. In some embodiments, the shape-changing portion may be locked in position to enhance stabilization of the annulus.

[0025] In some embodiments, the first stabilizing member includes a semicircular housing, a plurality of tethered anchors disposed within the housing, and at least one expandable balloon for driving the plurality of anchors into tissue of the valve annulus. In some  
10 embodiments, the device may include an inflation actuator for inflating the expandable balloon, a release actuator for releasing the anchors from the housing, and a cinching actuator for cinching a tether coupled with the tethered anchors to reduce a diameter of the valve annulus. The first stabilizing member may be configured to allowing driving of the plurality of anchors in any suitable direction or configuration. For example, in some embodiments the  
15 first stabilizing member will be configured for positioning under a heart valve annulus and for driving anchors upwards (or superiorly) into or through the annulus. In another embodiment, a stabilizing member may be configured for positioning above an annulus and for driving anchors downwards. Alternatively, a stabilizing member may be positioned outside a heart wall or other structure, with anchors driven inwardly. And as discussed  
20 above, these devices may be used to perform other cardiac and non-cardiac procedures, such as anchoring and cinching a gastroesophageal junction, bladder outlet or other structure.

[0026] As mentioned above, some embodiments also include at least a second stabilizing member movably coupled with the elongate shaft, wherein the second stabilizing member may be moved toward the first stabilizing member to grip and stabilize the valve annulus.

25 Optionally, such embodiments may also include one or more anchor receiving pieces coupled with the second stabilizing member for receiving distal ends of the plurality of anchors driven through the tissue of the valve annulus. In some embodiments, each of the first and second stabilizing members comprises a flexible rigidifying portion. Alternatively, each of the first and second stabilizing members may comprise a rigid member. Some embodiments may also  
30 include a handle near the proximal end of the shaft for moving the second stabilizing member toward the first stabilizing member to grip the valve annulus.

[0027] In alternative embodiments, either the first stabilizing member, the second stabilizing member or both may include any of a number of annulus treatment devices. For example, in one embodiment a stabilizing member may include an energy deliver device, such as a radiofrequency delivery device, for transmitting energy to a valve annulus to constrict the annular tissue. In another embodiment, a stabilizing member may include a mechanical support member or other deployable device that is couplable with a valve annulus. For example, a shape memory stent may be coupled with a stabilizing member such that when the stent is coupled with annular tissue and deployed, it shrinks longitudinally to reduce the diameter of the annulus. In other embodiments, multiple such stents may be used. These and other embodiments are described more fully below with reference to the drawing figures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Fig. 1 is a cross-sectional view of a heart with a flexible stabilization device being positioned for stabilizing a valve annulus, according to one embodiment of the present invention;

[0029] Figs. 1A and 1B are cross-sectional views of a valve leaflet, valve annulus, atrial wall and ventricular wall, with a stabilization device in place for stabilizing and exposing the annulus, according to one embodiment of the present invention;

[0030] Fig. 2 is a perspective view of a stabilization device having two stabilization members, according to one embodiment of the present invention;

[0031] Fig. 3 is a cross-sectional view of a valve leaflet, valve annulus, atrial wall and ventricular wall, with a stabilization device in place having upper and lower stabilization members, according to one embodiment of the present invention;

[0032] Fig. 4 shows a stabilization device as in Fig. 3 with a tethered clip placed in the valve annulus, according to one embodiment of the present invention;

[0033] Fig. 5 shows a stabilization device having a balloon-driven clip applier as its upper stabilizing member, according to one embodiment of the present invention;

[0034] Figs. 5A and 5B show a stabilization device having a balloon-driven hook applier as its upper stabilizing member, and a method for using same, according to one embodiment of the present invention;

[0035] Figs. 5C and 5D show a stabilization device having a balloon-driven hook applier as its upper stabilizing member, a lower stabilizing member carrying a hook receiver, and a method for using same, according to one embodiment of the present invention;

[0036] Fig. 6 is a perspective view of a balloon-driven hook applier for applying hooks to a cardiac valve annulus, according to one embodiment of the present invention;

[0037] Fig. 7 is a close-up view of the device in Fig. 6; and

[0038] Fig. 8 is a perspective view of a balloon-driven hook applier as in Figs. 6 and 7, with the balloon expanded and the hooks deployed, according to one embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[0039] Devices and methods of the present invention are generally used to facilitate transvascular, minimally invasive and other "less invasive" surgical procedures, by enhancing exposure, stabilization and/or the like of a tissue or structure upon which a procedure is to be performed. As discussed more fully above, "less invasive," for the purposes of this application, means any procedure that is less invasive than traditional, large-incision open surgical procedures. Thus, a less invasive procedure may be an open surgical procedure involving one or more relatively small incisions, a transvascular percutaneous procedure, a transvascular procedure via cut-down, a laparoscopic or other endoscopic procedure, or any procedure in which a goal is to minimize or reduce invasiveness to the patient may be considered less invasive.

[0040] The present application typically describes devices and methods for stabilization and/or exposure in the context of heart valve repair, and more specifically mitral valve repair to treat mitral regurgitation. Devices and methods of the invention may be used in any suitable procedure, however, both cardiac and non-cardiac. For example, they may be used in procedures to repair any heart valve, to repair an atrial-septal defect, to access and possibly perform a procedure from (or through) the coronary sinus, to place one or more pacemaker leads, to perform a cardiac ablation procedure such as ablating around pulmonary veins to treat atrial fibrillation, and/or the like. In other embodiments, the devices and methods may be used to enhance a laparoscopic or other endoscopic procedure on any part of the body, such as the bladder, stomach, gastroesophageal junction, vasculature, gall bladder, or the like. In some embodiments, for example, devices and methods include coupling multiple tethered

anchors to a valve annulus and cinching the annulus to reduce a diameter of the valve.

Similar devices and methods may be used, alternatively, to close or reduce the diameter of an atrial-septal defect, a gastroesophageal junction, or any other suitable body lumen, valve or other structure. Therefore, although the following description typically focuses on mitral

5 valve and other heart valve repair, such description should not be interpreted to limit the scope of the invention as defined by the claims.

[0041] Devices and methods of the invention generally provide for enhanced stabilization, exposure and/or treatment of a cardiac valve annulus. By "stabilize," it is meant that the annulus will be at least partially immobilized relative to the cardiac tissue surrounding the

10 annulus, at least partially delineated or exposed relative to cardiac tissue surrounding the annulus, or both. For example, in some instances "stabilization" may not involve immobilizing annular tissue but may instead involve moving or positioning annular tissue in such a way to allow enhanced visualization of that tissue relative to surrounding tissues.

Methods generally involve introducing a stabilizing member beneath one or more leaflets of a

15 heart valve to engage the ventricular side of the annulus at an intersection between the leaflets and the interior ventricular wall of the heart. The stabilizing member will usually be curved or C-shaped to conform to at least a portion of the ventricular side of the annulus, and force is applied to the stabilizing member to engage and stabilize the valve annulus.

[0042] In addition to stabilizing, methods and apparatus of the present invention may also

20 help expose, position, or delineate the valve annulus, to enhance the physician's ability to view and operate on the annular tissue. Some embodiments also include a second stabilizing member, to be introduced above the leaflets, allowing a physician to grasp or clamp annular tissue between the upper and lower stabilizing members for further stabilization. Various embodiments further provide for treatment of a valve annulus. For example, either the upper

25 or lower stabilizing member may include actuators or effectors for performing any one or more of a variety of interventions. For example, either or both stabilizing members may be adapted to deliver devices for constricting or reshaping the valve annulus to treat regurgitation or other conditions. The devices may comprise anchors, tethered anchors, rings, or the like for reinforcing or cinching the annulus. In a specific example, the stabilizing

30 member may be configured to hydraulically or otherwise deliver a series of tethered hooks, tethered clips or other tethered anchors or fasteners for engaging and cinching valve annulus tissue to decrease the diameter of a regurgitant valve. The stabilizer(s) will also be adaptable for delivering other therapies, including applying radiofrequency energy (or other heat

sources) to shrink the collagen tissue in the annulus, delivering bulking agents, delivering drugs and biological agents such as growth factors.

[0043] In most cases, the methods of the present invention will be performed on a beating heart. Access to the beating heart may be accomplished by any available technique, including intravascular, transthoracic, and the like. In addition to beating heart access, the methods of the present invention may be used for intravascular stopped heart access as well as stopped heart open chest procedures.

[0044] Referring now to Figure 1, a heart H is shown in cross section, with a stabilization device 100 introduced within the heart H. Generally, stabilization device 100 comprises an elongate body with at least a first stabilizing member 102 at its distal end for providing stabilization and/or exposure of a heart valve annulus. In some embodiments, the elongate body comprises a rigid shaft, while in other embodiments it comprises a flexible catheter, so that the first stabilizing member may be positioned in the heart H and under one or more valve leaflets to engage an valve annulus via a transvascular approach. Transvascular access may be gained, for example, through the internal jugular vein (not shown) to the superior vena cava SVC to the right atrium RA, across the interatrial septum to the left atrium LA, and then under one or more mitral valve leaflets MVL to a position within the left ventricle (LV) under the valve annulus (not shown). Alternatively, access to the heart may be achieved via the femoral vein and the inferior vena cava. In other embodiments, access may be gained via the coronary sinus (not shown) and through the atrial wall into the left atrium.

[0045] In other embodiments, access to the heart H may be transthoracic, with the stabilization device being introduced into the heart via an incision or port on the heart wall. Even open heart surgical procedures may benefit from methods and devices of the invention. Furthermore, some embodiments may be used to enhance procedures on the tricuspid valve annulus, adjacent the tricuspid valve leaflets TVL, or any other cardiac or vascular valve. Therefore, although the following description typically focuses on minimally invasive or less invasive mitral valve repair for treating mitral regurgitation, the invention is in no way limited to that use.

[0046] With reference to Figures 1A and 1B, a method for using stabilization device 100 is depicted in a cross-sectional view. First, as in Figure 1A, stabilizing member 102 is positioned in a desired location under a valve leaflet L and adjacent a ventricular wall VW. The valve annulus generally comprises an area of heart wall tissue at the junction of the

ventricular wall VW and the atrial wall AW that is relatively fibrous and, thus, significantly stronger than leaflet tissue and other heart wall tissue. Stabilizing member 102 may be advanced into position under the valve annulus by any suitable technique, some of which are described below in further detail. For example, using a stabilization device having a flexible elongate body as shown in Figure 1, stabilizing member 102 may be passed from the right atrium RA through the interatrial septum in the area of the foramen ovale (not shown--behind the aorta A), into the left atrium LA. Oftentimes, stabilizing member 102 will then naturally travel, upon further advancement, under the posterior valve leaflet to a position under the valve annulus VA, as shown in Figure 1A.

[0047] In some embodiments, stabilizing member 102 includes a shape-changing portion which enables stabilizing member 102 to conform to the shape of the valve annulus VA. The catheter may be introduced through the vasculature with the shape-changing stabilizing member in a generally straight, flexible configuration. Once it is in place beneath the leaflet at the intersection between the leaflet and the interior ventricular wall, the shape of stabilizing member 102 is changed to conform to the annulus and usually the shape is "locked" to provide sufficient stiffness or rigidity to permit the application of force from stabilizing member 102 to the annulus. Shaping and optionally locking stabilizing member 102 may be accomplished in any of a number of ways. For example, in some embodiments, a shape-changing portion may be sectioned, notched, slotted or segmented and one of more tensioning cords, wires or other tensioning devices coupled with the shape-changing portion may be used to shape and rigidify stabilizing member 102. A segmented stabilizing member, for example, may include multiple segments coupled with two tensioning cords, each cord providing a different direction of articulation to the stabilizing member. A first bend may be created by tensioning a first cord to give the stabilizing member a C-shape or similar shape to conform to the valve annulus, while a second bend may be created by tensioning a second cord to articulate the C-shaped member upwards against the annulus. In various embodiments, any configurations and combinations may be used to give stabilizing member 102 a desired shape.

[0048] In transthoracic and other embodiments, stabilizing member 102 may be pre-shaped, and the method may simply involve introducing stabilizing member 102 under the valve leaflets. The pre-shaped stabilizing member 102 may be rigid or formed from a shape memory material such as nitinol, spring stainless steel, or the like.

[0049] Once stabilizing member 102 is positioned under the annulus, force may be applied to stabilize the valve annulus VA, as shown in Figure 1B. Such force may be directed in any suitable direction to expose, position and/or stabilize the annulus. For example, upward and lateral force is shown in Figure 1B by the solid-headed arrow drawn from the center of stabilizing member 102. In other cases, only upward, only lateral, or any other suitable force(s) may be applied. With application of force to stabilizing member 102, the valve annulus VA is caused to rise or project outwardly, thus exposing the annulus for easier viewing and access. The applied force may also stabilize the valve annulus VA, also facilitating surgical procedures and visualization.

[0050] With reference now to Figure 2, one embodiment of a stabilization device 200 may include an upper or atrial stabilizing member 202, coupled with an outer shaft 210, and a lower or ventricular stabilizing member 204 coupled with an inner shaft 212. Upper stabilizing member 202 and lower stabilizing member 204 are typically adapted for placement above and below a valve annulus, such as the mitral valve annulus. Stabilizing members 202 and 204 will typically be formed from an elastic material having a geometry selected to engage and optionally shape or constrict the valve annulus. For example, the rings may be formed from shape memory alloy, such as nitinol, from a spring stainless steel, or the like. In other instances, however, the stabilizing members could be formed from an inflatable or other structure can be selectively rigidified *in situ*, such as a gooseneck or lockable element shaft, any of the rigidifying structures described above, or any other rigidifying structure.

[0051] As described above, the device 200 may be introduced to the left atrium of a beating heart, either transeptally or through an incision in the heart wall. Once in the atrium, the lower or ventricular stabilizing member will be introduced through the mitral valve opening, with a corner 206 of the stabilizing member typically being engaged against a commissure. The ventricular stabilizing member 204 may be adjusted so that it lies at a junction between the valve leaflet L and the ventricular wall VW, as illustrated in FIG. 3. The upper or atrial stabilizing member 202 may then be clamped down onto the upper surface of the annulus VA, typically by sliding outer shaft 210 down over inner shaft 212. Thus, the annulus will be circumferentially clamped between the stabilizing members, again as observed in FIG.3. Such clamping will stabilize the annulus relative to the remainder of the beating heart, thus facilitating subsequent minimally invasive surgical procedures. For example, and with reference now to Figure 4, a clip applier may be used to introduce individual tethered



clips 156 into the valve annulus VA. Exemplary clip appliers for applying tethered clips to a valve annulus are described more fully in U.S. Patent Application Serial No. 10/461043, which was previously incorporated by reference. Alternatively, atrial stabilizing member 202 could be replaced with a circular clip applier 220, as shown in FIG. 5. A stabilizing device  
5 employing such a clip applier could be used to simultaneously stabilize the annulus and deliver clips 222 using a clip driver, such as a balloon 224.

**[0052]** Although not illustrated, in some instances it may be desirable to provide a third stabilizing element on the exterior of the heart, optionally between the coronary sinus CS and circumflex artery CF or within the coronary sinus.

10 **[0053]** As is described further below, any stabilizing member, including an atrial stabilizing member, a ventricular stabilizing member, or both, may include one or more devices for treating a valve annulus. Such devices may include any suitable device for treating an annulus, and the present invention is not limited to any specific embodiments. For example, in some embodiments a stabilizing member comprises a housing for containing a plurality of  
15 tethered anchors and a system for delivering the anchors into annular tissue. "Anchors" may comprise curved hooks, straight hooks, barbed hooks, clips of any kind, T-tags, shape memory hooks, or any other suitable fastener(s). Delivery of anchors may be accomplished by any suitable device and technique, such as by hydraulic balloon delivery as discussed below. Alternatively, any other suitable treatment may be delivered to an annulus. For  
20 example, energy such as radiofrequency energy may be delivered to the annulus via a stabilizing member to constrict the annular tissue. Alternatively, a shape memory stent may be delivered to the annulus such that when deployed the stent longitudinally shrinks to constrict the annulus. In other embodiments, one or more drugs or bulking agents may be administered to the annulus. Therefore, although the following description focuses on  
25 delivery of a plurality of tethered hooks to a valve annulus, many other types of anchors and other treatment modalities may alternatively be delivered using devices and methods of the invention.

**[0054]** That being said, and referring now to Figures 5A and 5B, in one embodiment, upper stabilizing member 202 could be replaced with a circular hook applier 230, including a  
30 housing for multiple tethered hooks 232 and a hook driver such as a balloon 234. Again, hooks 232 may be replaced by any other anchors in various embodiments. Hooks 232 may be coupled to the device via a pivot mandrel 236, so that when balloon 234 is inflated, as in

Figure 5B, hooks 232 pivot around mandrel 236 to enter tissue of the valve annulus VA. Hydraulically driving curved hooks 232 in this way closely replicates the motion of a surgeon manually driving a suture needle into tissue and allows hooks 232 to be driven strongly into the tissue of the valve annulus VA. After hooks 232 are engaged with the valve annulus VA, they may be cinched, using the tether (not shown), to decrease the diameter of the annulus and thus the valve. The housing, the balloon 234 and the pivot mandrel 236 may be withdrawn before or after cinching.

[0055] As mentioned above, in various embodiments other anchor delivery mechanisms may be used, although one or more expandable balloons are used in one embodiment. For example, other hydraulic delivery systems may be used, anchors may be advanced into tissue using a pull-cord, or the like. In some embodiments, treatment devices and delivery mechanisms may be incorporated into lower/ventricular stabilizing member 204, rather than upper/atrial stabilizing member 202. In still other embodiments, some of which are described immediately below, both stabilizing members 202 and 204 may include devices for treatment of the valve annulus VA.

[0056] Additionally, and with reference now to Figures 5C and 5D, some embodiments may include one or more fasteners and fastener receiving pieces. For example, a circular hook applier 240, including multiple tethered hooks 242 on a pivot mandrel 246 and a balloon 244 may be disposed on the upper, atrial side of the valve annulus VA, and lower stabilizing member 204 may carry one or more receiving pieces 248 for receiving part of one or more of hooks 242. As shown in Figure 5D, when balloon 244 is inflated, it drives hooks 242 in a curved path through tissue of the valve annulus VA and into receiving piece 248. Receiving piece 248 may comprise any suitable material with any configuration for receiving and holding a portion of hooks 242. In some embodiments, for example, receiving piece 248 may comprise a Dacron strip, while in other embodiments the fastener and fastener receiving piece may be configured similar to a plastic garbage bag tie or the like. Any configuration is contemplated within the scope of the invention. In alternative embodiments, anchors may be driven from lower stabilizing member 204 into a receiving piece carried by upper stabilizing member 202.

[0057] Referring now to Figures 6, 7 and 8, one embodiment of a stabilizing and hook delivery device 260 is shown. Typically, hook delivery device 260 will include an elongate housing or shaft 261, which will house a series of hooks 264 coupled to housing 261 via a

pivot mandrel 266 and coupled to one another via a tether 268. Housing 262 will also include one or more expandable balloons 262 for driving hooks 264. Housing 262 may be flexible or rigid in various embodiments. Of course, any number, size and shape of hooks 264 (or other anchors) may be included in housing 261. Tether 268 may be one long piece of material or  
5 two or more pieces and may comprise any suitable material, such as suture, suture-like material, a Dacron strip or the like. Pivot mandrel 268 may also have any suitable configuration and be made of any suitable material. In one embodiment, mandrel 268 is made of a metal such as stainless steel, titanium or nitinol. Expandable balloon 262 may have any suitable size and configuration. In some embodiments, more than one balloon may  
10 be used. As shown in Figure 8, inflating balloon 262 drives hooks 264 in a curvilinear path (arrows) into adjacent tissue (not shown). Hooks thus driven into tissue of a cardiac valve annulus may then be cinched, via tether 268, to reduce the valve diameter, thus treating or ameliorating valve regurgitation.

**[0058]** Although the foregoing is a complete and accurate description of the present  
15 invention, the description provided above is for exemplary purposes only, and variations may be made to the embodiments described without departing from the scope of the invention. Thus, the above description should not be construed to limit the scope of the invention as described in the appended claims.